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RD2009-09

Registration Decision

Dimethenamid-P

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Registration Decision for Dimethenamid-P

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Dimethenamid-P Technical Herbicide and Frontier Max Herbicide, containing the technical grade active ingredient dimethenamid-P, to control certain annual grassy weeds as well as redroot pigweed, eastern black nightshade and yellow nutsedge in corn, soybeans, dry common beans, dry bulb onions, transplanted cabbage, peanuts and non-bearing grape vines.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2009-04, *Dimethenamid-P*. This Registration Decision² describes this stage of the PMRA's regulatory process for dimethenamid-P and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-04. This decision is consistent with the proposed registration decision stated in PRD2009-04.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-04, *Dimethenamid-P*, that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/prma.

What Is Dimethenamid-P?

Dimethenamid-P is a herbicide that inhibits protein and flavonoid biosynthesis. These biochemical effects result in inhibition of cell division and tissue differentiation in susceptible plant species, with death of these plant species occurring prior to or soon after emergence from the soil.

Frontier Max Herbicide contains dimethenamid-P and can be applied as a preplant incorporated, preplant, pre-emergence or postemergence treatment to control the labelled annual grassy weeds plus redroot pigweed, Eastern black nightshade and yellow nutsedge in a variety of crops.

Health Considerations

Can Approved Uses of Dimethenamid-P Affect Human Health?

Dimethenamid-P is unlikely to affect your health when used according to label directions.

Potential exposure to dimethenamid-P may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when dimethenamid-P products are used according to label directions.

The technical grade active ingredient dimethenamid-P was highly toxic by the oral route in animals. It also tested positive for dermal sensitization. Consequently, the statements "DANGER-POISON" and "Potential Skin Sensitizer" are required on the label.

The end-use product Frontier Max Herbicide is of moderate toxicity when given as a single oral dose to rats, and is moderately irritating to the eye of rabbits. It also tested positive for dermal sensitization. Consequently, the statements "WARNING-POISON", "Warning-Eye Irritant" and "Potential Skin Sensitizer" are required on the label.

Dimethenamid-P did not cause cancer in animals and was not genotoxic. There was also no indication that dimethenamid-P caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of dimethenamid-P over longer periods of time were decreased body-weight gain and increased liver weights with associated cellular and clinical chemistry effects.

When dimethenamid-P was given to pregnant animals, no effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to dimethenamid-P than the adult animal. Because of this observation, extra protective measures beyond those that are normally applied were not required.

The risk assessment protects against adverse effects from dimethenamid-P by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As the metabolism of dimethenamid-P and dimethenamid (racemic mixture), were demonstrated to be the same, all the residue data generated with dimethenamid is bridged to dimethenamid-P. Aggregate dietary intake estimates (food plus water) revealed that children 1–2 years old, the subpopulation which would ingest the most dimethenamid and/or dimethenamid-P relative to body weight, is expected to be exposed to 10.1% or less of the acceptable daily intake. Based on these estimates, the chronic dietary risk from dimethenamid and dimethenamid-P is not of concern for all segments of the population. Dimethenamid is not carcinogenic. Therefore, a chronic cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects at dose levels relevant to dietary consumption. Consequently, a single dose of dimethenamid or dimethenamid-P is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using dimethenamid on field and sweet corn, soybeans, dry common beans, dry bulb onions, transplanted cabbage and peanuts were acceptable. The MRLs established to cover residues of dimethenamid will be used to cover residues of dimethenamid-P.

Occupational Health Risks From Handling Frontier Max Herbicide

Occupational health risks are not of concern when Frontier Max Herbicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply as well as field workers who re-enter freshly treated fields can come into direct contact with Frontier Max Herbicide residues on the skin. The label will specify that workers handling Frontier Max Herbicide must wear a long-sleeved shirt, long pants, coveralls and chemical resistant gloves and shoes plus socks during mixing, loading, application, clean-up and repair. In addition, the label will specify that goggles or a face shield must be worn during mixing/loading.

The label also specifies that workers must not enter treated fields for 24 hours. Taking into consideration these label requirements, risks to agricultural workers are not of concern.

Risks in Residential and Other Non-Occupational Environments

For bystanders, the exposure is expected to be much less than that of field workers and is considered negligible when the product is used according to label directions. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Dimethenamid-P Is Introduced Into the Environment?

When used according to label directions, Frontier Max Herbicide does not pose an unacceptable risk to the environment. However, precautionary measures are required to mitigate the potential risks of dimethenamid-P to terrestrial and aquatic plants and small wild mammals.

Dimethenamid-P enters the environment when used as a herbicide for various crops. In the terrestrial environment, dimethenamid-P is non-persistent in aerobic soil and moderately persistent in anaerobic soil. It has a potential for leaching in soils. Biotransformation is expected to be the main route of dissipation in soil for dimethenamid-P.

Dimethenamid-P can enter the aquatic environment through spray drift and run-off from the site of application. In aquatic systems, dimethenamid-P is slightly persistent under aerobic and anaerobic conditions. Biotransformation, rather than hydrolysis and photolysis, is expected to be the main route of dissipation for dimethenamid-P in aquatic systems. Dimethenamid-P is very soluble in water. Based on the environmental fate characteristics, limited run-off of the dimethenamid-P and transformation products is expected. Monitoring data using dimethenamid as a surrogate indicate that dimethenamid-P can be found in surface water sources.

At the maximum application rate of 930 g a.i./ha, a risk assessment identified the potential risks of dimethenamid-P to terrestrial and aquatic plants and mammalian herbivores, for which further mitigation measures are required.

Value Considerations

What Is the Value of Frontier Max Herbicide?

Frontier Max Herbicide controls specific grassy weeds and the broadleaf weeds, redroot pigweed, Eastern black nightshade and yellow nutsedge in a variety of crops

Frontier Max Herbicide can be applied as a preplant incorporated, preplant, or pre-emergence treatment in field corn, sweet corn, seed corn, soybeans, dry common beans, transplanted cabbage and peanuts; as an early postemergence treatment in field corn; and can also be directly applied under established first year and second year non-bearing grape vines. A single application of Frontier Max Herbicide at 756–963 mL/hectare (544–693 g a.i./ha) provides control of the labelled annual grassy weeds plus redroot pigweed, Eastern black nightshade and yellow nutsedge. The required application rate for weed control is determined by the application timing, soil texture and soil organic matter content. Medium and fine textured soils with higher organic matter content require higher application rates while coarse textured soils with lower organic matter content require lower application rates. Frontier Max Herbicide at 1.29 L/hectare (930 g a.i./ha) can be applied at the loop stage of dry bulb onions grown on muck soils for suppression of yellow nutsedge.

Frontier Herbicide (Registration Number 23462), which is comprised of the racemic mixture of dimethenamid (45:55 of r- and s-stereoisomers), was cited as a precedent product for Frontier Max Herbicide. Herbicidal activity has been found to be attributed mainly to s-isomer of dimethenamid (i.e. dimethenamid-P) which is the active ingredient of Frontier Max Herbicide. Frontier Max Herbicide provides the same efficacy and crop tolerance as Frontier Herbicide, but will allow for a 45% reduction in the total amount of total dimethenamid applied to field crops as compared to the currently registered racemic mixture of Frontier Herbicide. This results in a reduced herbicidal load on the environment and reduced worker exposure.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Frontier Max Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

- Workers handling Frontier Max Herbicide must wear a long-sleeved shirt, long pants, coveralls and chemical resistant gloves and shoes plus socks during mixing, loading, application, clean-up and repair. In addition, goggles or face shield must be worn during mixing/loading. The label also specifies that workers must not enter treated fields for 24 hours. Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Environment

- Precautionary label statements are required as a result of the environmental risk assessment.
- A buffer zone of 3 m is calculated for the use of Frontier Max Herbicide for protection of terrestrial plants.
- A buffer zone of 1 m is calculated for the use of Frontier Max Herbicide for protection of aquatic habitats.
- A label statement of "Toxic to aquatic organisms, non-target terrestrial plants and small wild mammals" is required to avoid the potential risks of dimethenamid-P to these organisms.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

⁵

As per subsection 35(1) of the *Pest Control Products Act*.

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